



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|------------------------|------------------|
| 10/031,289 | 05/31/2002 | Vega Masignani | PP01639.102; 2300-1639 | 6882 |

7590 05/07/2004

Chiron Corporation
Intellectual Property Department R440
PO Box 8097
Emeryville, CA 94662-8097

| |
|----------|
| EXAMINER |
|----------|

DEVI, SARVAMANGALA J N

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1645

DATE MAILED: 05/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|--------------------------------------|---|--|
| <p align="center">Office Action Summary</p> | Application No. 10/031,289 | Applicant(s) MASIGNANI ET AL. | |
| | Examiner S. Devi, Ph.D. | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-10 and 13-24 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-4, 6-10 and 13-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Lack of Unity of Invention(s)

1) Claims 5, 11 and 12 have been canceled.

Claims 1, 3, 4, 6, 7, 9 and 10 have been amended via the amendment filed 05/31/02.

New claims 14-24 have been added via the amendment filed 05/31/02.

Claims 1-4, 6-10 and 13-24 are under prosecution.

2) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program.

3) The instant inventions lack unity under PCT Rule 13.1 and 13.2:

- I. Claims 1-4, 6, 8, 10 and 16, drawn to a fragment of a protein disclosed in WO 99/36544 or a protein fragment with at least 50% sequence identity thereto comprising at least one antigenic determinant and a composition comprising the same.
- II. Claims 9, 14, 17 and 18, drawn to a nucleic acid encoding a fragment of a protein disclosed in WO 99/36544 or a protein fragment with at least 50% sequence identity thereto comprising at least one antigenic determinant and a composition comprising the same.
- III. Claims 7 and 15, drawn to an antibody which recognizes a fragment of a protein disclosed in WO 99/36544 or a protein fragment with at least 50% sequence identity thereto comprising at least one antigenic determinant and a composition comprising the same.
- IV. Claims 13 and 20, drawn to a method of treating a patient by administering a composition comprising a fragment of a protein disclosed in WO 99/36544 or a protein fragment with at least 50% sequence identity thereto comprising at least one antigenic determinant.
- V. Claim 19, drawn to a method of treating a patient by administering a composition comprising an antibody to a fragment of a protein disclosed in WO 99/36544 or a protein fragment with at least 50% sequence identity thereto comprising at least one antigenic determinant.

- VI. Claims 21 and 22, drawn to a method of treating a patient by administering a composition comprising a nucleic acid encoding a fragment of a protein disclosed in WO 99/36544 or a protein fragment with at least 50% sequence identity thereto comprising at least one antigenic determinant.
- VII. Claim 23, drawn to a method of detecting the presence of a meningococcal protein in a biological sample using an antibody to a protein fragment disclosed in WO 99/36544.
- VIII. Claim 24, drawn to a method of detecting the presence of meningococcal antibodies in a biological sample using a protein fragment disclosed in WO 99/36544.

4) Inventions I-VIII lack unity of inventions due to the absence of a special technical feature. The special technical feature of the first claimed product, i.e., invention I, is a fragment of a protein disclosed in WO 99/36544, or a protein fragment with at least 50% sequence identity thereto containing at least one antigenic determinant. However, such a protein fragment was already known in the art at the time of the invention. For example, as documented in the international search report, Biegel *et al.* (*J. Bacteriol.* 181: 2895-2901, May 1999) taught the amino acid sequence, EYLKEKN, which corresponds to the sequence EYLKEKN present in ORF38-1 and ORF38a from WO 99/36544, and antibodies thereto. Therefore, the special technical feature of invention I does not define over the prior art. The special technical features of inventions II and III respectively are a nucleic acid and an antibody, which do not share significant structural features among themselves or with the protein product of invention I. Inventions IV and VIII are drawn to first and second methods of using the protein product of invention I. Although the product of invention I and the first method of using the same is a permitted combination under PCT Rule 13.2, in the instant case, since the product is already disclosed in the art, the special technical feature does not define over the prior art. Technically, the absence of special technical feature permits the separation of the methods of using or making the product from the product itself. The special technical features of the rest of the inventions V, VI and VIII are the various methods delineated above, which do share significant method steps, reagents or compositions used in the methods.

5) After electing one of the above-identified inventions or claim sets, Applicants should further elect a single recited protein or DNA sequence, or a single antibody specific to one of the recited protein sequences for

Serial No. 10/031,289

Art Unit: 1645

examination. For whichever protein or DNA product is elected, Applicants should identify a single specific SEQ ID number. Prior to allowance, non-elected subject matter will be required to be deleted from any allowable claims. Applicants are advised that examination will be restricted to only the elected SEQ ID NO. and should not to be construed as a species election.

6) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A telephone message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER